



# UNITED STATES PATENT AND TRADEMARK OFFICE

*ch*  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/855,542

05/16/2001

Rajesh Manchanda

BERLX-100

9728

23599

7590

03/09/2007

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.

2200 CLARENDON BLVD.

SUITE 1400

ARLINGTON, VA 22201

EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

2 MONTHS

03/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

---

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

**MAILED**  
**MAR 09 2007**  
**GROUP 1600**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/855,542  
Filing Date: May 16, 2001  
Appellant(s): MANCHANDA, RAJESH

---

John Sopp  
Millen, White, Zelano & Branigan, P.C.  
Arlington Courthouse Plaza I  
2200 Clarendon Blvd. Suite 1400  
Arlington, Virginia 22201  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed November 14, 2006 appealing from the Office action mailed March 14, 2006.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,262,175	Solanki	11-1993
6,881,396	Cyr	1-2005

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, 6, 8-10, 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solanki US Patent 5,262,175 in view of Cyr et al US Patent US 6,881,396.

The instant claims are directed to compositions comprising a radionuclide such as Tc-99m, a targeting agent preferably a peptide, and iodide ions.

Solanki teaches the use of weak oxidizing agents such as iodine, iodophores and povidone iodine to stabilize the radiopharmaceutical complex compositions. (col 2, lines 1-8). Solanki teaches preparing a Tc-99 containing composition by mixing lyophilized Tc-99m hexamethylpropyleneaminoxime (HMPAO) complex with 0.4 mg of sodium iodide or potassium iodide. (see col 7, line 55- col 8, line 50). Solanki then claims methods of stabilizing a radiopharmaceutical complex with weak oxidizing agents such as iodine, iodophores and povidone-iodine. (see col 8, line 50-col 9, line 5). Solanki teaches the addition of weak oxidizing agents such as iodine salts to radiopharmaceutical complexes including Tc-labeled compositions. The sodium iodide or potassium iodide and further the iodine component of Solanki is viewed to meet the instant limitation "iodide ion or iodide ion generating compound," because even iodine component can read on the term "compound which generates iodide ions." Solanki only fails to specifically recite the use of depreotide in his formulations.

Cyr is used to establish the state of art in using targeting peptides and stabilizers to increase the shelf life of radiopharmaceuticals (see col 5-15). Cry specifically teaches the use of Tc-labelled somatostatin receptor-binding peptide deproetide (col 15, line 1-col 18; col 44, lines 36-59). Cyr also encourages the addition of any suitable pharmaceutical agent for preparing his formulations (col 15, lines 8-40). Applicant is also put in notice that Cyr's effective filing date antedates the effective filing date of the instant application, because Cyr's CIP parent application adequately described the instantly relied teachings. (see attached priority documents at pages 22-27 of US App 09/695,360, now abandoned). Thus, Cyr is a competent prior art.

It has been held *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to combine a weak oxidizing agent such as iodine salts of Solanki with the Tc-labelled formulations of Cyr, because both formulations are directed for the same purpose and combining them would flow logically from their having been individually taught in prior art.

Further, as stated by Solanki, the ordinary skill in the art would have had a reasonable expectation of success in achieving a stable radiopharmaceutical formulation when adding iodine salt described by Solanki , to a Tc-labelled containing radiopharmaceutical compositions.

**(10) Response to Argument**

Appellant argues unconvincingly in pages 4-5 of the Brief filed November 14, 2006 that Cyr and Solanki are directed to stabilizing different types of radiopharmaceuticals and therefore, there is no motivation to use Solanki's weak oxidizing agent to the peptide radiopharmaceuticals of Cyr. Examiner notes that since it is generally known in the art to use a weak oxidizing agent such as iodide to improve stability of radiopharmaceutical agents, such knowledge would have been available to the one of ordinary skill in the art to employ. Here, since both cited art are in the same field of endeavor, one of ordinary skill in the art would have had a reasonable expectation of success in employing the teachings provided by both references. The primary reference only suggests a number of halogen releasing agents for use as stabilizers. Thus, therefore selecting such agents to reach the claimed intended purpose (i.e., to stabilize a peptide radiopharmaceutical composition) would have had a reasonable expectation of success.

Appellant's arguments in page 5 of the Brief filed November 14, 2006 averring Solanki expressing the undesired use of antioxidant are not convincing. Examiner notes that Solanki clearly teaches that in general, antioxidant can be added (See col. 3, lines 5-6). In the case of Tc-99m HMPAO complex, the antioxidant Ascorbic acid does not change the rate of degradation. Examiner notes that the effect of ascorbic acid is directed merely to the specific case of Tc-99m HMPAO complex. As discussed above, it is known that potassium iodide can stabilize the radiopharmaceuticals because it can minimize the excess stannous ion, which is responsible for the degradation (see col. 5,

Art Unit: 1617

lines 5-12). Therefore, in view of such properties, one of ordinary skill in the art would have been motivated to employ iodide to stabilize the peptide Tc-99m complex disclosed in Cyr.

Appellant's arguments in page 6 of the Brief filed November 14, 2006 averring the cited prior arts' failure to teach iodide ions or a compound which releases or generated iodide ions are unconvincing. Examiner states that such lines of arguments are not persuasive, because not only Solanki discloses the use of sodium or potassium iodides, but also the use of iodine itself. Clearly, the language of iodine in Solanki at least read on compounds that generate iodide ions. Furthermore, Solanki's invention relies on the use of halogen releasing agents including iodide ions (col 2, lines 1-11). Specifically, Solanki teaches the use of other oxidizing agents including iodine or its derivatives. Thus, Solanki clearly provides for the use of halogen releasing agents such as iodide ions in his compositions. Furthermore, in col. 7, lines 45-49 teaches that potassium iodide can be used to overcome the elute age restriction and also decrease the temperature because of its endothermic properties. And from the earlier part of Solanki, lower temperature can be used to stabilize the radiopharmaceutical complex (See col. 5, line 15).

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

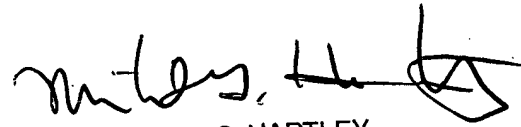
Art Unit: 1617

Respectfully submitted,




San-ming Hui  
Primary Examiner  
Art Unit 1617

Conferees:



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER